DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 19, 2000, from 9 a.m. to 5 p.m., and on October 20, 2000, from 8:30 a.m. to 4 p.m.

Location: National Institutes of Health, 9000 Rockville Pike, Bldg. 10, Clinical Center, Jack Masur Auditorium, Bethesda, MD.

Contact Person: Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, Woodmont II Bldg., 1451 Rockville Pike, Rockville, MD 20752, 419-259-6211, or John M. Treacy, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 19, 2000, the committee will meet in closed session. On October 20, 2000, the committee will discuss dose response using data from approved antihypertensive drugs.

Procedure: On October 20, 2000, from 8:30 a.m. to 4 p.m., the meeting will be open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by

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October 12, 2000. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9:30 a.m. on October 20, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 12, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On October 19, 2000, from 9 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information regarding pending investigational new drug applications and new drug applications (5 U.S.C. 552b(c)(4)).

Noti. of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 27 Sept 00 September 22, 2000

Benard A. Schwetz

Acting Deputy Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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